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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/806,801

04/04/2001

Staffan Folestad

1103326-0659

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01/04/2005

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EXAMINER

JACKSON, ANDRE K

ART UNIT

PAPER NUMBER

2856

DATE MAILED: 01/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,801

Applicant(s)

FOLESTAD ET AL.

Examiner

André K. Jackson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6-23 and 25-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-23 and 25-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-3,6-11,17 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammond et al. in view of Trygstad and Wong.

Regarding claim 1, Hammond et al. disclose "Spectrophotometric analysis" which has a means for feeding one sample through at least one predetermined analyzing position (Column 4, lines 1-11) and a means for temporarily fixing the sample in the analyzing position, where the fixing means comprises a first (8) and a second (12) holding part arranged at the analyzing position and where the holding parts are adapted to move between an open position when the sample is provided for analysis and a closed position when the sample is analyzed. Hammond et al. do not disclose where the first and second holding parts define apertures within the parts and where the first and second apertures together define an effective aperture in the closed position. However, Trygstad discloses in "Measurement of transmission spectra of pharmaceutical tablets" where the first and second holding parts defines apertures within the parts and where the first and second apertures together define an effective aperture in the closed position (Figures 1 and 2; 30,36). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made

to modify Hammond et al. to include where the first and second holding parts defines apertures within the parts and where the first and second apertures together define an effective aperture in the closed position. By adding this feature the artisan would be able to analyze tablets of various sizes. Wong discloses in the patent entitled "A non-pressure dependency infrared absorption spectra recording, sample cell" where at the analyzing position the holding parts are adapted to move between an open position when the sample is provided for analysis and a closed position when the sample is analyzed (Abstract; Columns 1 and 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hammond et al. to include where at the analyzing position the holding parts are adapted to move between an open position when the sample is provided for analysis and a closed position when the sample is analyzed. By adding this feature the apparatus would be able to hold the sample at one position during analyzing.

Regarding claim 2, Hammond et al. do not disclose where the first and second holding parts are located on opposite sides of the sample when in the closed position. However, Trygstad discloses where the first and second holding parts are located on opposite sides of the sample when in the closed position (Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hammond et al. to include where the first and second holding parts are located on opposite sides of the

sample when in the closed position as taught by Trygstad. By adding this arrangement the sample would remain in a stable position.

Regarding claim 3, Hammond et al. disclose where the first and second holding parts do not contact the sample in the open position (Column 12, lines 22-52).

Regarding claim 6, Hammond et al. disclose where the first and second holding parts each define a first and second compartment, which together define a predetermined volume (Figure 2).

Regarding claim 7, Hammond et al. disclose where the means for feeding samples through the analyzing position comprises one pre-alignment means for receiving and holding a sample during transport of the sample to the analyzing position (Figure 2).

Regarding claims 8 and 9, Hammond et al. do not disclose where the pre-alignment means comprises an elastically compressible member for flexibly engaging the sample. It is considered a design choice to have an elastically compressible member for flexibly engaging the sample to keep the sample from chipping or breaking.

Regarding claim 10, Hammond et al. disclose where the pre-alignment means comprise a spring-loaded arm for embracing the sample (Figure 2).

Regarding claim 11, Hammond et al. disclose where spring-loaded arm and a part of the feeding means are provided with an indentation for receiving the sample (Figure 1).

Regarding claim 17, Hammond et al. disclose where the sample is a solid dosage form (Figure 2).

Regarding claim 26, Hammond et al. disclose where the dosage is a tablet (Figure 2).

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hammond et al. in view of Trygstad and in further view of Soloman.

Regarding claim 13, neither Hammond et al. nor Trygstad disclose where the rotating feeder wheel is connected to a sample receiver, which provides the feeder with samples to be analyzed. However, Soloman discloses where the rotating feeder wheel is connected to a sample receiver, which provides the feeder with samples to be analyzed (Figures 1-2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include where the rotating feeder wheel is connected to a sample receiver which provides the feeder with samples to be analyzed since it would provide an even distribution of tablets.

3. Claims 12, 14-16 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammond et al. in view of Trygstad and Schilling.

Regarding claim 12, neither Hammond et al. nor Trygstad disclose where the means for feeding samples sequentially through the analyzing position is a rotating feeder wheel comprising at least one pre-alignment means for receiving at least one sample. However, Schilling discloses a means for feeding samples sequentially through the analyzing position is a rotating feeder wheel comprising

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at least one pre-alignment means for receiving at least one sample (Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include a means for feeding samples sequentially through the analyzing position is a rotating feeder wheel comprising at least one pre-alignment means for receiving at least one sample as taught by Schilling since it would make it easier to analyze more samples in a shorter period of time.

Regarding claim 14, Hammond et al. do not disclose where the sample receiver is an on-line sample receiver and provides the pre-alignment means with samples. However, Schilling discloses where the sample receiver is an on-line sample receiver and provides the pre-alignment means with samples (Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include where the sample receiver is an on-line sample receiver and which provides the pre-alignment means with samples as taught by Schilling since this would help to give an accurate measurement for the sample.

Regarding claim 15, Hammond et al. do not disclose where the sample receiver is an at-line sample receiver, which provides the pre-alignment means with samples. However, Schilling discloses where the sample receiver is an at-line sample receiver, which provides the pre-alignment means with samples. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include where the sample receiver

is an at-line sample receiver, which provides the pre-alignment means with samples as taught by Schilling since this would aid in having the measurement of the samples more accurate.

Regarding claim 16, Hammond et al. do not disclose where the at-line sample receiver comprise a conical rotating part defining the bottom of an open vessel with cylindrical geometry, where samples fall upon the conical rotating part to be sequentially aligned before entering the pre-alignment means in the feeder wheel. However, Schilling discloses where the at-line sample receiver comprise a conical rotating part defining the bottom of an open vessel with cylindrical geometry, where samples fall upon the conical rotating part to be sequentially aligned before entering the pre-alignment means in the feeder wheel (Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include where the at-line sample receiver comprise a conical rotating part defining the bottom of an open vessel with cylindrical geometry, where samples fall upon the conical rotating part to be sequentially aligned before entering the pre-alignment means in the feeder wheel as taught by Schilling since this would make it easier to sort the tablets.

Regarding claim 25, Hammond et al. do not disclose where the sample receiver is a transport line connected on-line to an instrument which performs a tabletting process. However, Schilling discloses where the sample receiver is a transport line connected on-line to an instrument which performs a tabletting

process (Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include where the sample receiver is a transport line connected on-line to an instrument which performs a tableting process as taught by Schilling since this would ease in the measuring of the sample.

4. Claims 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammond et al. in view of Schilling and Trygstad.

Regarding claim 18, Hammond et al. disclose a means for temporarily fixing the sample at the analyzing position. Hammond et al. disclose that the predetermined position is the analyzing position where the sample is clamped. The claim calls for at least one predetermined analyzing position Hammond et al. disclose two analyzing positions. In the second analyzing position the sample is displaced. Hammond et al. do not disclose feeding a sample sequentially through the sample presentation apparatus. However, Schilling discloses where feeding a sample sequentially through the sample presentation apparatus (Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Hammond et al. to include where feeding a sample sequentially through the sample presentation apparatus as taught by Schilling since this would make it easier for the samples to be placed in the analyzing position. Hammond et al. does not disclose an open position to allow the sample to be transported to an ejection position. However, the invention of Hammond et al. has to have the holding parts open in order to eject the sample to place

another one in place. Hammond et al. do not disclose where the first and second holding parts define apertures within the parts and where the first and second apertures together define an effective aperture in the closed position. However, Trygstad discloses where the first and second holding parts define apertures within the parts (Figures 1 and 2; 30,36). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hammond et al. to include where the first and second holding parts defines apertures within the parts. By adding this feature the artisan would be able to analyze tablets of various sizes.

Regarding claim 19, Hammond et al. disclose where the measurement is performed by irradiating the sample with at least one measuring beam while the sample is temporarily fixed (Figure 2).

Regarding claim 20, Hammond et al. disclose where the measurement is an optical measurement (Abstract).

Regarding claim 21, Hammond et al. disclose where the optical measurement is carried out by means of near-infrared spectrometry (Abstract).

Regarding claim 22, Hammond et al. disclose where the optical measurement is carried out by means of near-infrared spectrometry (Abstract).

Regarding claim 23, it is considered a design choice and well within the purview of the skilled artisan to have the radiation beam a microwave beam since this would give the artisan a beam with a shorter wavelength and a more precise measurement.

Regarding claim 27, Hammond et al. disclose a means for feeding one or more samples sequentially through at least one predetermined analyzing position, where at least one measuring radiation beam irradiates the sample when the sample is located in the analyzing position (Column 4, lines 1-11) and a means for temporarily fixing the sample in the analyzing position, where the fixing means comprises a first (8) and a second (12) holding part arranged at the analyzing position and where the holding parts are adapted to move between an open position when the sample is provided for analysis and a closed position when the sample is analyzed. Meanwhile, Wong discloses where at the analyzing position the holding parts are adapted to move between an open position when the sample is provided for analysis and a closed position when the sample is analyzed (Abstract; Columns 1 and 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hammond et al. to include where at the analyzing position the holding parts are adapted to move between an open position when the sample is provided for analysis and a closed position when the sample is analyzed. By adding this feature the apparatus would be able to hold the sample at one position during analyzing.

Regarding claim 28, Hammond et al. disclose a means for feeding one or more samples sequentially through the sample presentation apparatus having at least one predetermined analyzing position, where at least one measuring radiation beam irradiates the sample when the sample is located in the analyzing

position (Column 4, lines 1-11) and temporarily fixing the sample in the analyzing position in a closed fixed position by means of a two-piece fixing means including a first (8) and a second (12) holding part arranged at the analyzing position.

Hammond et al. do not disclose an open position to allow the sample to be transported to an ejection position. However, the invention of Hammond et al. has to have the holding parts open in order to eject the sample to place another one in place.

Response to Arguments

5. Applicant's arguments filed 10/05/04 have been fully considered but they are not persuasive.

Applicants have argued that Hammond et al. do not disclose that the first and second holding parts are configured to move between an open and closed position at the analyzing position. Hammond et al. disclose that the predetermined position is the analyzing position where the sample is clamped (Column 4, lines 1-11,23-29; Column 5 lines, 9-19,24-57). The claims call for at least one analyzing position Hammond discloses two analyzing positions. In the second analyzing position the sample is displaced. Claims 18 and 28 do not require that the holding parts be opened at the analyzing position as does claims 1 and 27. Applicants describe paragraph [0018] as not demonstrating the opened position. The Examiner agrees that the sample is clamped and then an analysis is performed on the sample by a spectrophotometer. Applicants are

arguing that the holder is manually inserted into a "spectrometer" for analysis.

The claim is not concerned with how the sample is presented to the analysis apparatus.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to André K. Jackson whose telephone number is (571) 272-2196. The examiner can normally be reached on Mon.-Thurs. 7AM-4PM.

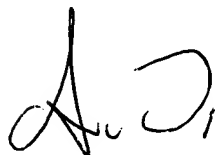
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on (571) 272-2208. The

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fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.J.



December 7, 2004



HEZRON WILLIAMS
SUPERVISORY PATENT EXAMINER
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